

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claims 1-53 (Canceled).

54. (New): A process for preparing a crystalline form of topotecan monohydrochloride pentahydrate having an x-ray diffraction pattern that is substantially the same as Figure 1, wherein the process comprises:

[a] forming an aqueous organic solvent mixture containing topotecan monohydrochloride, wherein the aqueous solvent of the aqueous organic solvent mixture is a 0.05 N aqueous hydrochloric acid solution and wherein the organic solvent of the aqueous organic solvent mixture is selected from the group consisting of acetone and tetrahydrofuran, and wherein the ratio of organic solvent to aqueous solvent in the aqueous organic solvent mixture is from about 1.5:1 to about 3:1;

[b] recrystallizing the topotecan monohydrochloride from the aqueous organic solvent mixture to precipitate said crystalline form of topotecan monohydrochloride pentahydrate; and

[c] collecting, by filtration, said crystalline form of topotecan monohydrochloride pentahydrate.

55. (New): The process according to claim 54, wherein said crystalline form of topotecan monohydrochloride pentahydrate provides an x-ray diffraction pattern having peaks at $4.5 \pm 0.1 (\text{ }^\circ 2\theta)$, $6.4 \pm 0.1 (\text{ }^\circ 2\theta)$, $7.1 \pm 0.1 (\text{ }^\circ 2\theta)$, $9.0 \pm 0.1 (\text{ }^\circ 2\theta)$, $10.1 \pm 0.1 (\text{ }^\circ 2\theta)$, $11.5 \pm 0.1 (\text{ }^\circ 2\theta)$, $12.6 \pm 0.1 (\text{ }^\circ 2\theta)$, $13.1 \pm 0.1 (\text{ }^\circ 2\theta)$, $14.1 \pm 0.1 (\text{ }^\circ 2\theta)$, $15.5 \pm 0.1 (\text{ }^\circ 2\theta)$, $17.9 \pm 0.1 (\text{ }^\circ 2\theta)$, $18.7 \pm 0.1 (\text{ }^\circ 2\theta)$, $20.0 \pm 0.1 (\text{ }^\circ 2\theta)$, $20.3 \pm 0.1 (\text{ }^\circ 2\theta)$, $21.1 \pm 0.1 (\text{ }^\circ 2\theta)$, $21.8 \pm 0.1 (\text{ }^\circ 2\theta)$, $23.0 \pm 0.1 (\text{ }^\circ 2\theta)$, $24.8 \pm 0.1 (\text{ }^\circ 2\theta)$, $25.6 \pm 0.1 (\text{ }^\circ 2\theta)$, $26.6 \pm 0.1 (\text{ }^\circ 2\theta)$, $27.2 \pm 0.1 (\text{ }^\circ 2\theta)$, and $28.9 \pm 0.1 (\text{ }^\circ 2\theta)$.

56. (New): The process according to claim 54, wherein the organic solvent is acetone.

57. (New): The process according to claim 56, wherein the ratio of the volume of acetone to aqueous hydrochloric acid is about 2:1.

58. (New): The process according to claim 54, further comprising:

- first dissolving topotecan monohydrochloride in a heated aqueous organic solvent solution mixture;
- recrystallizing the topotecan monohydrochloride pentahydrate from the heated solution by cooling the solution; and
- filtering the resulting crystallized topotecan monohydrochloride pentahydrate product and drying.

59. (New): The process according to claim 58, wherein the heated aqueous organic solvent mixture is cooled at a rate in the range of about 0.1°C/min to about 1°C/min.

60. (New): The process according to claim 59, wherein the cooling rate is about 0.25°C/min.

61. (New): The process according to claim 58, wherein the heated solution is cooled to a temperature of about room temperature to about 0°C.

62. (New): The process according to claim 58, wherein the aqueous organic solvent mixture comprises acetone and a 0.05 N aqueous hydrochloric acid solution heated to a temperature of about 58°C.

63. (New): The process according to claim 59, wherein the aqueous organic solvent mixture comprises acetone and a 0.05 N aqueous hydrochloric acid solution heated to a temperature of about 58°C.

64. (New): The process according to claim 62, wherein the ratio of the volume of acetone to aqueous hydrochloric acid is about 2:1.

65. (New): The process according to claim 63, wherein the ratio of the volume of acetone to aqueous hydrochloric acid is about 2:1.

66. (New): A process for preparing a crystalline form of topotecan monohydrochloride pentahydrate having an inverse second derivative FT-IR spectrum for the spectral region of 1800 cm^{-1} - 1500 cm^{-1} that is substantially the same as Figure 3, wherein the process comprises:

[a] forming an aqueous organic solvent mixture containing topotecan monohydrochloride, wherein the aqueous solvent of the aqueous organic solvent mixture is a 0.05 N aqueous hydrochloric acid solution and wherein the organic solvent of the aqueous organic solvent mixture is selected from the group consisting of acetone and tetrahydrofuran, and wherein the ratio of organic solvent to aqueous solvent in the aqueous organic solvent mixture is from about 1.5:1 to about 3:1;

[b] recrystallizing the topotecan monohydrochloride from the aqueous organic solvent mixture to precipitate said crystalline form of topotecan monohydrochloride pentahydrate; and

[c] collecting, by filtration, said crystalline form of topotecan monohydrochloride pentahydrate.

67. (New): The process according to claim 66, wherein said crystalline form of topotecan monohydrochloride pentahydrate provides an FT-IR spectrum having peaks at $1754 \pm 2\text{ cm}^{-1}$, $1745 \pm 2\text{ cm}^{-1}$, $1740 \pm 2\text{ cm}^{-1}$, $1658 \pm 2\text{ cm}^{-1}$, $1649 \pm 2\text{ cm}^{-1}$, $1596 \pm 2\text{ cm}^{-1}$, $1584 \pm 2\text{ cm}^{-1}$, and $1507 \pm 2\text{ cm}^{-1}$.

68. (New): The process according to claim 66, wherein the organic solvent is acetone.

69. (New): The process according to claim 68, wherein the ratio of the volume of acetone to aqueous hydrochloric acid is about 2:1.

70. (New): The process according to claim 66, further comprising:

- first dissolving topotecan monohydrochloride in a heated aqueous organic solvent solution mixture;

- recrystallizing the topotecan monohydrochloride pentahydrate from the heated solution by cooling the solution; and
- filtering the resulting crystallized topotecan monohydrochloride pentahydrate product and drying.

71. (New): The process according to claim 70, wherein the heated aqueous organic solvent mixture is cooled at a rate in the range of about 0.1°C/min to about 1°C/min.

72. (New): The process according to claim 71, wherein the cooling rate is about 0.25°C/min.

73. (New): The process according to claim 70, wherein the heated solution is cooled to a temperature of about room temperature to about 0°C.

74. (New): The process according to claim 70, wherein the aqueous organic solvent mixture comprises acetone and a 0.05 N aqueous hydrochloric acid solution heated to a temperature of about 58°C.

75. (New): The process according to claim 71, wherein the aqueous organic solvent mixture comprises acetone and a 0.05 N aqueous hydrochloric acid solution heated to a temperature of about 58°C.

76. (New): The process according to claim 74, wherein the ratio of the volume of acetone to aqueous hydrochloric acid is about 2:1.

77. (New): The process according to claim 75, wherein the ratio of the volume of acetone to aqueous hydrochloric acid is about 2:1.

78. (New): A process for preparing a crystalline form of topotecan monohydrochloride pentahydrate having an x-ray diffraction pattern that is substantially the same as Figure 1, wherein the process comprises:

[a] forming an aqueous organic solvent mixture containing topotecan monohydrochloride, wherein the aqueous solvent of the aqueous organic solvent mixture is a

0.05 N aqueous hydrochloric acid solution and wherein the organic solvent of the aqueous organic solvent mixture is selected from the group consisting of acetone, tetrahydrofuran, and n-propanol, and wherein the ratio of organic solvent to aqueous solvent in the aqueous organic solvent mixture is from about 2:1 to about 8:1;

[b] slurring the topotecan monohydrochloride with the aqueous organic solvent mixture to form said crystalline form of topotecan monohydrochloride pentahydrate; and

[c] collecting, by filtration, said crystalline form of topotecan monohydrochloride pentahydrate.

79. (New): The process according to claim 78, wherein said crystalline form of topotecan monohydrochloride pentahydrate provides an x-ray diffraction pattern having peaks at $4.5 \pm 0.1 (\text{ }^\circ 2\theta)$, $6.4 \pm 0.1 (\text{ }^\circ 2\theta)$, $7.1 \pm 0.1 (\text{ }^\circ 2\theta)$, $9.0 \pm 0.1 (\text{ }^\circ 2\theta)$, $10.1 \pm 0.1 (\text{ }^\circ 2\theta)$, $11.5 \pm 0.1 (\text{ }^\circ 2\theta)$, $12.6 \pm 0.1 (\text{ }^\circ 2\theta)$, $13.1 \pm 0.1 (\text{ }^\circ 2\theta)$, $14.1 \pm 0.1 (\text{ }^\circ 2\theta)$, $15.5 \pm 0.1 (\text{ }^\circ 2\theta)$, $17.9 \pm 0.1 (\text{ }^\circ 2\theta)$, $18.7 \pm 0.1 (\text{ }^\circ 2\theta)$, $20.0 \pm 0.1 (\text{ }^\circ 2\theta)$, $20.3 \pm 0.1 (\text{ }^\circ 2\theta)$, $21.1 \pm 0.1 (\text{ }^\circ 2\theta)$, $21.8 \pm 0.1 (\text{ }^\circ 2\theta)$, $23.0 \pm 0.1 (\text{ }^\circ 2\theta)$, $24.8 \pm 0.1 (\text{ }^\circ 2\theta)$, $25.6 \pm 0.1 (\text{ }^\circ 2\theta)$, $26.6 \pm 0.1 (\text{ }^\circ 2\theta)$, $27.2 \pm 0.1 (\text{ }^\circ 2\theta)$, and $28.9 \pm 0.1 (\text{ }^\circ 2\theta)$.

80. (New): The process according to claim 78, wherein the organic solvent is selected from acetone and tetrahydrofuran.

81. (New): The process according to claim 78, wherein the organic solvent is acetone.

82. (New): The process according to claim 81, wherein the ratio of the volume of acetone to aqueous hydrochloric acid is about 8:1.

83. (New): A process for preparing a crystalline form of topotecan monohydrochloride pentahydrate having an inverse second derivative FT-IR spectrum for the spectral region of 1800 cm^{-1} - 1500 cm^{-1} that is substantially the same as Figure 3, wherein the process comprises:

[a] forming an aqueous organic solvent mixture containing topotecan monohydrochloride, wherein the aqueous solvent of the aqueous organic solvent mixture is a 0.05 N aqueous hydrochloric acid solution and wherein the organic solvent of the aqueous

organic solvent mixture is selected from the group consisting of acetone, tetrahydrofuran, and n-propanol, and wherein the ratio of organic solvent to aqueous solvent in the aqueous organic solvent mixture is from about 2:1 to about 8:1;

[b] slurring the topotecan monohydrochloride with the aqueous organic solvent mixture to form said crystalline form of topotecan monohydrochloride pentahydrate; and

[c] collecting, by filtration, said crystalline form of topotecan monohydrochloride pentahydrate.

84. (New): The process according to claim 83, wherein said crystalline form of topotecan monohydrochloride pentahydrate provides an FT-IR spectrum having peaks at $1754 \pm 2 \text{ cm}^{-1}$, $1745 \pm 2 \text{ cm}^{-1}$, $1740 \pm 2 \text{ cm}^{-1}$, $1658 \pm 2 \text{ cm}^{-1}$, $1649 \pm 2 \text{ cm}^{-1}$, $1596 \pm 2 \text{ cm}^{-1}$, $1584 \pm 2 \text{ cm}^{-1}$, and $1507 \pm 2 \text{ cm}^{-1}$.

85. (New): The process according to claim 83, wherein the organic solvent is selected from acetone and tetrahydrofuran.

86. (New): The process according to claim 83, wherein the organic solvent is acetone.

87. (New): The process according to claim 86, wherein the ratio of the volume of acetone to aqueous hydrochloric acid is about 8:1.